Distal embolization is common after directional atherectomy in coronary arteries and saphenous vein grafts

Coronary embolization is a complication of coronary intervention procedures. The incidence, predictors, and clinical significance of this phenomenon during directional atherectomy were examined in 111 consecutive patients who underwent directional atherectomy to 120 lesions. Distal embolization occurred in 31 (28%) of the patients. It was noted mainly in the saphenous vein graft group of patients (12 [48%] of 25) versus the native coronary group (19 [22% of 86]; $p = 0.01$). Clinical predictors were age and de novo lesions. Morphologic predictors were larger artery size, larger postprocedure minimal luminal diameter, calcific lesions, and type C lesions. The only difference in clinical outcome was a longer hospitalization in the distal embolization group with 3.9 ± 3.7 days versus the rest of the patients 2.4 ± 2.4 days ($p = 0.01$). In the majority of patients there was no significant adverse clinical outcome. (AM HEART J 1995;129:430-5.)

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Coronary artery embolization is a rare complication of native vessels after elective coronary interventional procedures, especially in patients with stable angina.[1-3] It is more often encountered in acute coronary thrombosis and acute myocardial infarction, after thrombolysis, and in old, degenerated saphenous vein grafts.[4-6] Histopathologic studies have shown that the embolic material is composed mainly of lipid-rich atherosclerotic core fragments and thrombus.[7] The clinical consequences of coronary embolization are dependent both on size and on the number of embolic particles. Coronary embolization is demonstrated angiographically in some patients; however, the majority of events are the result of microemboli, and it is difficult to document them angiographically. These events are more common than realized and are characterized by creatine phosphokinase (CPK) and creatine kinase (CK)-MB isoenzyme elevation with or without chest discomfort, electrocardiographic changes during or after the procedure, and in a small percentage of patients, Q-wave myocardial infarction. Directional atherectomy as a device for coronary artery intervention has the potential to cause distal embolization resulting from the incision of the atherosclerotic plaque that expose the core elements, the dotter effect of the relatively large device, and the angioplasty effect that accompanies balloon inflation. All of these effects may potentially dislodge atherosclerotic material distally during passage of the lesion. The purpose of this report is to document the incidence and the clinical, procedural, and morphologic predictors of distal embolization and the outcome of patients who underwent directional atherectomy in native coronary arteries and saphenous vein grafts.

METHODS

Study patients. Data were collected on 111 consecutive patients (120 lesions) who underwent directional atherectomy at Emory University hospital Atlanta, Ga., from March 1992 to April 1993. Clinical and procedural information was obtained from the medical records.

Inclusion criteria. Patients were included if they had symptomatic coronary artery disease or evidence of myocardial ischemia during exercise or pharmacologic stress testing and had angiographically documented stenosis, with >50% luminal diameter narrowing in the proximal or

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Table I. Clinical and demographic predictors for coronary embolization

	Distal embolization			
	With (n = 33)	*Without (n = 78)*	*p Value*	*Odds ratio*
Age (yr)	64.2 ± 10	59.8 ± 9	0.03	1.13
Male gender	30 (90.1)	66 (84.6%)	NS	—
Unstable angina	16 (48.5%)	35 (44.8%)	NS	—
Prior CABG	11 (33.3%)	14 (17.9)	0.07	2.29
SVG age (yr)	9.1 ± 6	6.3 ± 12	0.04	1.09
De novo lesions	29 (87.8%)	54 (69.2%)	0.032	3.22

CABG, Coronary artery bypass graft; *SVG*, saphenous vein graft; *NS*, not significant.

the mid portion of a vessel with a reference segment diameter ≥2.5 mm. Patients with acute myocardial infarction or CPK elevation at baseline were excluded.

Definitions. Successful atherectomy procedure was defined as <50% residual stenosis after angioplasty with at least a 20% reduction in the original stenosis (angiographic success) without in-hospital death, Q-wave myocardial infarction, or bypass surgery (clinical success). Q-wave myocardial infarction was defined as the development of a new pathologic significant Q wave in at least two contiguous leads. Angiographic embolization was defined as slow-flow phenomenon, new filling defect, or an abrupt vessel cut-off that developed during the procedure. Clinical distal embolization was defined to be present in patients with angiographic documentation of reduction of the lesion to <50% diameter stenosis at the lesion site. The following criteria were also present: CPK or CK-MB isoenzymes five times baseline level, ST-T and/or T-wave changes in ECG after the procedure, and chest pain that started during the procedure and persisted after the procedure. Abrupt closures or acute myocardial infarctions that occurred after the procedure and involved CPK rise or ECG changes were excluded from the definition.

Coronary atherectomy procedure. The technique of directional atherectomy has been described elsewhere.[8, 9] After baseline coronary angiography the patients were prepared in a fashion similar to standard percutaneous transluminal coronary angioplasty (PTCA). Premedications included 325 mg of aspirin. A 10F or 11F sheath was placed in the femoral artery; 10,000 U of heparin was administered intravenously and was repeated as necessary in doses sufficient to maintain the activated clotting time >300. The target lesion was crossed with a 0.014-inch guide wire in a manner similar to that of standard PTCA. Balloon dilatation to facilitate atherectomy angioplasty was performed initially in 21 (17%) lesions. SCA-1, SCA-EX, and SCA-1-7G catheters (Devices for Vascular Intervention, Redwood City, Calif.) were used. A mean of 2.0 ± 1.1 introductions of the catheter was performed, and 5.1 ± 3.1 samples were retrieved. Balloon postdilatation was performed in an attempt to achieve a final lesion diameter as close as possible to the normal size of the vessel in 27 (22%) lesions.

Table II. Frequency of preprocedural angiographic characteristics

Lesion characteristic	*Frequency (n = 120)*
Eccentric	92 (76%)
Calcific	20 (16%)
Thrombus	14 (12%)
Branch point	31 (25.8%)
Length >12 mm	28 (23.3%)
Ulceration	38 (32%)
Lesion angle >45 degrees	18 (15%)
TIMI flow	2.64 ± 0.54
Mean baseline luminal diameter	0.61 ± 0.4
Percentage of diameter narrowing	81.3% ± 8.5%

TIMI, Thrombolysis in myocardial infarction.

Angiographic analysis. The cineangiograms were assessed for preprocedural angiographic characteristics; presence of a thrombus, calcium, branch point, eccentricity, or lesion type according to the American Heart Association/American College of Cardiology (AHA/ACC) classification; and coronary thrombolysis in myocardial infarction flow. Measurements of artery size, minimal luminal diameter before and after atherectomy/angioplasty, and lesion length were evaluated from two angiographic projections, if available, by means of a computerized digitized quantitative angiography system.

Follow-up. Follow-up was performed by clinic visit or telephone contact at 6 and 12 months. Forty (36%) patients underwent repeat angiography. Clinical restenosis was considered to be present if symptoms recurred; angiographic restenosis was considered to be present if the diameter stenosis at follow-up was >50% at the treated site.

Statistics. Data are presented as mean ± SD. Dichotomous variables were analyzed by using the chi-squared method. Statistical significance was attained when the probability value was ≤0.05. Multivariate analysis was performed with logistic regression. Percentages are reported to the nearest first decimal point where appropriate. All statistics were performed by use of the SAS program.[10]

Table III. Angiographic characteristics and procedural predictors of distal embolization

Characteristics	*Distal Embolization* *With (n = 33)*	*Distal Embolization* *Without (n = 78)*	*p Value (Univariate)*	*Odds Ratio*
Artery size (mm)	3.6 ± 0.9	3.2 ± 0.6	0.008	1.18
Eccentricity	25 (83.3%)	67 (85.8%)	NS	—
Calcification	10 (30.3%)	8 (10.2%)	0.009	3.80
Type C lesion	16 (48.4%)	21 (26.9%)	0.03	2.55
Thrombus	7 (21.2%)	7 (8.9%)	0.07	2.73
Branch point	8 (24.2%)	23 (29.4%)	NS	—
Ulceration	13 (39.3%)	25 (32.1%)	NS	—
Mean length (mm)	7.59 ± 4.6	7.44 ± 4.58	NS	—
Length >12 mm	8 (24.2%)	20 (25.6%)	NS	—
Post MLD (mm)	2.8 ± 0.6	3.2 ± 0.8	0.04	—
Balloon predilatation	9 (27.2%)	10 (12.8%)	0.07	2.55
SCA-I cutter	8 (24.4%)	28 (35.9%)	NS	—
SCA-EX cutter	17 (51.5%)	40 (51.2%)	NS	—
SCA-I-7G cutter	8 (24.4%)	10 (12.8%)	NS	—
No. of passes	2.27 ± 1.2	1.89 ± 1.1	NS	—
No. of samples	4.57 ± 3.7	4.06 ± 3.0	NS	—
Balloon postdilatation	10 (30.3%)	15 (19.2%)	NS	—

RESULTS

Clinical characteristics. One hundred eleven patients underwent directional atherectomy to 120 lesions (86 patients with lesions in the native coronary artery and 25 patients with lesions in saphenous vein grafts). Nine patients had atherectomy to two sites during the same procedure. The mean age of the patients was 61 ± 9.7 years; 86% were men and 14% were women. Seventy-three percent of the patients had angina III or IV. Thirty (25%) procedures were performed on restenotic lesions, and 25 (22%) patients had previously undergone coronary artery bypass graft. Mean graft age was 78 ± 45 months. Table I summarizes the demographic and clinical predictors of distal embolization.

Preprocedural angiographic characteristics. Atherectomy was performed in 120 lesions; 80% of these were classified as types B and C according to the AHA/ACC lesion characterization. Lesion angiographic characteristics are shown in Table II. Ninety-three (77%) of the lesions were aortoostial and proximal in location. Artery distribution was as follows: 3% in the left main artery, 44% in the left anterior descending artery, 14% in the left circumflex artery, and 17% in the right coronary artery. Twenty-three percent of the lesions were in saphenous vein grafts. Morphologic predictors for distal embolization are listed in Table III.

Procedural characteristics. The SCA-EX was the most frequently used atherectomy cutter; it was used in 60 (50%) of the lesions. The SCA-1 catheter was used in 39 (32%) and the SCA-7G catheter was used in 21 (18%) of the lesions. The 6F and the 7F atherectomy cutters were the largest catheters used in 50 (42%) and 68 (57%) of the lesions, respectively. There were no independent procedural predictors for distal embolization. Angiographic overall success was obtained in 96% of lesions; clinical success, defined as angiographic success without major complications, was achieved in 90% of patients (92% in native coronaries vs 81% in saphenous vein grafts). Diameter of stenosis was reduced from a mean baseline of 81% ± 8% to 12.2% ± 10%, with an increase of MLD from 0.61 ± 0.4 mm to 2.94 ± 0.7 mm. Nine patients had atherectomy in two sites during the same procedure with angiographic success of 89%.

Complications. Angiographic and clinical complications are listed in Table IV. Among 111 patients who underwent directional atherectomy, clinical distal embolization occurred in 33 (30%) of patients; however, angiographic complications were recognized in only 15 (14%) patients. Nine patients had atherectomy at two sites during the same procedure; 5 (55%) of the 9 patients had distal embolization during the procedure. Cardiac enzyme rise was noted in 45 (50%) patients: CPK >200 U with CK-MB isoenzymes 5x baseline. ST-T changes during and after the procedures were noted in 53 (48%) patients. Distal embolization was more common in patients who underwent atherectomy to saphenous vein grafts (12 [48%]) as compared with the native coronary group (19 [22%]), $p = 0.02$. There was a higher rate of major complications (Q-wave myocardial infarction, emergent coronary artery bypass graft, abrupt

Table IV. Angiographic and clinical complications of 120 lesions in 111 patients

Complication	*n (%)*
Intimal tear	17 (14.1%)
Severe dissection	4 (3.3%)
Side closure	2 (1.6%)
Angiographic embolization	12 (10%)
Clinical distal embolization	33 (29.7%)
Abrupt closure	6 (5%)
Stent implantation	1 (0.8%)
Q-wave myocardial infarction	5 (4.5%)
Emergency CABG	2 (1.8%)
Death	0
Groin repair	2 (1.8%)
Groin hematoma	14 (12.6%)

Abbreviation as in Table I.

Table V. Clinical outcome at 6-month follow-up

	Distal Embolization		
Outcome	*With (n = 33)*	*Without (n = 78)*	*p Value*
Hospital length (days)	3.9 ± 3.7	2.4 ± 2.4	0.01
Death	1 (3.0%)	2 (2.54%)	NS
Recurrence of angina	11 (33.3%)	30 (38.4%)	NS
Repeat angiogram	14 (42.4%)	26 (33.3%)	NS
Angiographic restenosis	9 (27.2%)	20 (25.6%)	NS
Repeat nonsurgical intervention	5 (15.1%)	11 (14.1%)	NS
CABG	2 (6.0%)	5 (6.4%)	NS
Myocardial infarction	0	0	NS
Decreased in functional capacity	1 (3%)	1 (1.2%)	NS

Abbreviations as in Table I.

closure) among patients undergoing atherectomy to saphenous vein grafts than among patients undergoing atherectomy to native coronaries (36% vs 16%; $p = 0.007$).

Clinical outcome and follow-up. The only significant clinical outcome difference between the groups of patients with and without distal embolization was the length of hospital stay after the procedure, 3.9 ± 3.7 days versus 2.4 ± 2.4 days, respectively ($p = 0.01$). Of the 111 patients, 40 (36%) had recurrence of symptoms and underwent angiographic follow-up; and 29 (72.5%) of those 40 had restenosis at the previous atherectomized site. The cumulative 6-month clinical outcome is shown in Table V.

Predictors of distal embolization (clinical and angiographic). For these analyses, patients were divided into two groups: those with clinical distal embolization and those without distal embolization. The two groups were compared by clinical characteristics, baseline angiographic features, and procedural variables (Tables I and III). Thirty-three patients had distal embolization and 78 patients did not. The most important univariate predictors of distal embolization were age ($p = 0.03$), not-previously-dilated lesions ($p = 0.03$; odds ratio 3.22), artery size ($p = 0.008$), calcification ($p = 0.009$; odds ratio 3.80) and type C lesions ($p = 0.03$; odds ratio 2.55). Device type and size, number of passes, and samples retrieved were not predictors for distal embolization; however, there was a tendency for embolization when balloon predilatation was performed ($p = 0.07$; odds ratio 2.55).

DISCUSSION

The occurrence of CPK elevation and ECG abnormalities after coronary interventions with or without angiographic evidence of coronary embolization has been described, especially in old, degenerated vein grafts. This phenomenon is likely the result of embolization of thrombotic or atheromatous material into the distal coronary artery. In the current retrospective study, we used a clinical definition for distal embolization and attempted to determine the incidence and clinical and morphologic predictors in patients undergoing directional atherectomy and the significance of this phenomenon on the outcome of these patients. Distal embolization has been commonly defined by using angiographic criteria such as slow-flow phenomenon, loss of a distal branch, or a new filling defect that occurs during the procedure. In this study, these angiographic criteria were noted in only 10% of the patients and in one third who fulfilled the clinical criteria of distal embolization. Histopathologic studies have demonstrated microemboli that were only evident angiographically. Therefore the absence of angiographic findings does not rule out distal embolization. Recent studies have shown a correlation between the presence of coronary emboli and the development of postprocedural ECG abnormalities and rise in CPK level in the absence of intimal tear, acute closure, or spasm.[11-18] Therefore we suggest that a clinical definition for distal embolization should be used.[14, 15] Our study showed a high incidence of use in CPK level and ST-T ECG changes after directional atherectomy (33% and 47%, respectively).

Predictors. In the present study, the clinical predictors were age, previously undilated lesions, atherectomy to saphenous vein grafts, and saphenous vein graft age. The morphologic predictors were calcified lesions and type C lesions. Presence of a thrombus was not an independent predictor of distal embolization ($p = 0.07$). Further analysis showed that calcified lesions and complex lesions were more common in older patients and in previously undilated lesions. It appears that more samples of tissue were retrieved among the patients with previously undilated lesions. These findings suggest that careful morphologic characterization of the lesion before the procedure is an important factor in selection of patients for atherectomy. It would be helpful to use features such as degree of calcification, tissue friability, and presence of thrombus; these features may assist in predicting patients at high risk. Atherectomy resulted in a higher rate of complications in patients with saphenous vein grafts. A composite of all complications including distal embolization occurred in 72% of this group. A higher complication rate was noted among patients who underwent atherectomy of different sites during the same procedure; that rate may simply reflect the complexity of the procedure.

Potential mechanisms for distal embolization after atherectomy. The fundamental mechanism of coronary atherectomy is conceived to be excision of atherosclerotic plaque. In this series, a mean of 5.1 ± 3.1 samples per procedure were retrieved. The atherectomy device is chosen in patients with high atherosclerotic mass, and the excision of a friable plaque may liberate atherosclerotic core fragments distally. Dottering the lesion by passing a relatively large profile device through a friable plaque and incomplete retrieval of the specimen by the nosecone may contribute to distal embolization. The artery size and postprocedure minimal luminal diameter were independent predictors for distal embolization; however, to obtain a larger postprocedural diameter (12% ± 1% residual narrowing in our series), the operator may need to perform more cuts, and this may increase the risk of distal embolization.

Follow-up. Patients with distal embolization had chest discomfort that persisted for several hours. This discomfort was not associated with hemodynamic changes and did not necessitate additional treatment. The only impact on outcome was the length of hospitalization after the procedure. This may be the result of the reluctance of the physician to discharge patients with high CPK levels. Clinical follow-up revealed a low incidence of adverse events. There was no difference in the cumulative risk of death, myocardial infarction, or need for bypass surgery between the patients with embolization during atherectomy compared to those who did not have embolization (9% vs 8.9%, respectively). Repeat coronary angiography was available in only 40 (36%) patients, primarily those with clinical restenosis. In patients who underwent follow-up angiography, there was no significant difference in the restenosis rate (64% in patients with distal embolization vs 79% in patients without); left ventriculography at follow-up demonstrated similar function compared with baseline before the atherectomy in patients with distal embolization. It appears that distal embolization did not change the restenosis rate, and left ventricle function, heart failure symptoms, and subsequent cardiac events were not adversely affected in the patients with embolization.

Study limitations. This study was retrospective and nonrandomized, and the high incidence of distal embolization may be the result of selected patients with high atherosclerotic mass lesions. However, many patients with unfavorable characteristics were excluded. Whether distal embolization affected left ventricular function is not known because of incomplete assessment of left ventricular function in all patients after the procedure. Finally, the rate of embolization by this definition is unknown for balloon angioplasty or other devices and may also be higher than expected.

Conclusions. Directional atherectomy is a new technique for treating atherosclerotic heart disease and can be performed with a high success rate. This study used a strict definition of distal embolization to demonstrate that directional atherectomy is associated with a high rate of clinical distal embolization in native coronary arteries and saphenous vein grafts; analysis suggested that age, de novo lesions, saphenous vein grafts, calcified arteries, and complex lesions are the most powerful predictors. The occurrence of distal embolization was correlated with a larger vessel diameter and higher minimal luminal diameter after the procedure. It appears that the majority of patients with distal embolization did not have significant adverse effects. Further randomized studies comparing directional atherectomy to balloon angioplasty and other new devices are needed.

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